(1) The plutonium is contained in a medical device designed for individual

human application; or

- (2) The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Appendix A, Table A-2, of this part, and in which the radioactivity is essentially uniformly distributed: or
- (3) The plutonium is shipped in a single package containing no more than an A<sub>2</sub> quantity of plutonium in any isotope or form, and is shipped in accordance with §71.5; or
- (4) The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the Commission.

(b) Nothing in paragraph (a) of this section is to be interpreted as removing or diminishing the requirements of

§73.24 of this chapter.

(c) For a shipment of plutonium by air which is subject to paragraph (a)(4) of this section, the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

 $[60\ FR\ 50264,\ Sept.\ 28,\ 1995,\ as\ amended\ at\ 69\ FR\ 3795,\ Jan.\ 26,\ 2004]$ 

## §71.89 Opening instructions.

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with 10 CFR 20.1906(e).

# § 71.91 Records.

- (a) Each licensee shall maintain, for a period of 3 years after shipment, a record of each shipment of licensed material not exempt under §71.10, showing where applicable—
- (1) Identification of the packaging by model number and serial number:
- (2) Verification that there are no significant defects in the packaging, as shipped;
- (3) Volume and identification of coolant;

- (4) Type and quantity of licensed material in each package, and the total quantity of each shipment;
- (5) For each item of irradiated fissile material—
- (i) Identification by model number and serial number;
- (ii) Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and
- (iii) Any abnormal or unusual condition relevant to radiation safety;
  - (6) Date of the shipment;
- (7) For fissile packages and for Type B packages, any special controls exercised:
- (8) Name and address of the transferee;
- (9) Address to which the shipment was made; and
- (10) Results of the determinations required by §71.87 and by the conditions of the package approval.
- (b) Each certificate holder shall maintain, for a period of 3 years after the life of the packaging to which they apply, records identifying the packaging by model number, serial number, and date of manufacture.
- (c) The licensee, certificate holder, and an applicant for a CoC, shall make available to the Commission for inspection, upon reasonable notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.
- (d) The licensee, certificate holder, and an applicant for a CoC shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by §71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for 3

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years after the life of the packaging to which they apply.

[60 FR 50264, Sept. 28, 1995, as amended at 69 FR 3795, Jan. 26, 2004]

#### §71.93 Inspection and tests.

- (a) The licensee, certificate holder, and applicant for a CoC shall permit the Commission, at all reasonable times, to inspect the licensed material, packaging, premises, and facilities in which the licensed material or packaging is used, provided, constructed, fabricated, tested, stored, or shipped.
- (b) The licensee, certificate holder, and applicant for a CoC shall perform, and permit the Commission to perform, any tests the Commission deems necessary or appropriate for the administration of the regulations in this chapter.
- (c) The certificate holder and applicant for a CoC shall notify the NRC, in accordance with §71.1, 45 days in advance of starting fabrication of the first packaging under a CoC. This paragraph applies to any packaging used for the shipment of licensed material which has either—
- (1) A decay heat load in excess of 5 kW; or
- (2) A maximum normal operating pressure in excess of 103 kPa (15 lbf/in²) gauge.

[69 FR 3796, Jan. 26, 2004]

### §71.95 Reports.

- (a) The licensee, after requesting the certificate holder's input, shall submit a written report to the Commission of—
- (1) Instances in which there is a significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use; or
- (2) Details of any defects with safety significance in any NRC-approved Type B or fissile material packaging, after first use.
- (3) Instances in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.
- (b) The licensee shall submit a written report to the Commission of instances in which the conditions in the certificate of compliance were not followed during a shipment.

- (c) Each licensee shall submit, in accordance with §71.1, a written report required by paragraph (a) or (b) of this section within 60 days of the event or discovery of the event. The licensee shall also provide a copy of each report submitted to the NRC to the applicable certificate holder. Written reports prepared under other regulations may be submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. Using an appropriate method listed in §71.1(a), the licensee shall report to: ATTN: Document Control Desk, Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards. These written reports must include the following:
- (1) A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.
- (2) A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of part 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event.
- (i) Status of components or systems that were inoperable at the start of the event and that contributed to the event:
- (ii) Dates and approximate times of occurrences;
- (iii) The cause of each component or system failure or personnel error, if known;
- (iv) The failure mode, mechanism, and effect of each failed component, if known;
- (v) A list of systems or secondary functions that were also affected for failures of components with multiple functions;
- (vi) The method of discovery of each component or system failure or procedural error;
- (vii) For each human performance-related root cause, a discussion of the cause(s) and circumstances;
- (viii) The manufacturer and model number (or other identification) of